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EXAMINER

REICHLE, KARIN M

ART UNIT

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3761

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Election/Restrictions

1. Claims 3-13 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the replies filed on 10-19-04 and 5-31-06.

Response to Amendment

2. The amendments to the abstract and the specification filed 6-15-07 have not been entered since they do not comply with 37 CFR 1.121. The abstract has not been presented on a separate page from the amendments to the specification. Therefore, see paragraph 3 infra.

Specification

3. The disclosure is objected to because of the following informalities: 1) Is the structure of claims 3-10 and the abstract and that on page 5, lines 1-5 and Examples 5-6 one and the same? If so, note the density of the former, i.e. 4 grams per cubic centimeter, as compared to the latter, i.e. 0.4 grams per cubic centimeter. Should the densities be the same? 2) At the very least, see also discussion in paragraphs 5-7 infra, as best understood the addition of glycerol monolaurate (GML) to the tampon or absorbent structure as now claimed in new claims 14-15 is inconsistent with the description of the remainder of the application. Specifically, the description at, e.g., page 10, lines 3-8 discloses that GML is added to the lyocell material, i.e. the tampon or the

Art Unit: 3761

absorbent structure, and such makes the lyocell more resistant to toxic shock syndrome, i.e. affects the characteristics of the lyocell (Note also the teachings of Huber '598 discussed in the prior art rejections infra) yet the manner in which such is claimed, i.e. "tampon comprising an absorbent structure consisting essentially of lyocell fibers" (the terminology "consisting essentially of" limits the scope of the absorbent structure to the specified fibers and that which does not materially affect the basic and novel characteristics of such absorbent structure) as claimed in claim 1 and "tampon" or "absorbent structure" "further comprising glycerol monolaurate" as claimed in claims 14-15, respectively, infers it does not. A clear consistent description of the invention should be set forth throughout the application.

Appropriate correction is required.

Claim Objections

4. Claim 15 is objected to because of the following informalities: On line 1 "glycerol" should be --glycerol--. Also "structure of claim 1, further comprising" should be --tampon of claim 1 wherein the absorbent structure further comprises--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 1-2 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language "absorbent structure consisting essentially of lyocell fibers" of claim 1 is unclear, see the discussion in the paragraphs 3 and 7, i.e. don't know what "the basic and novel

Art Unit: 3761

characteristics” of the absorbent structure are. In regard to claim 15, this claim now requires the absorbent structure further comprise glycerol monolaurate, i.e. GML. However, as set forth in claim 1 the absorbent structure is set forth as “essentially consisting of” lyocell fibers.

Therefore, the scope of the claims now unclear and/or inconsistent, i.e. does the absorbent structure in claim 1 consist essentially of lyocell fibers? Comprise such fibers? Does the absorbent structure of claim 15 comprise such fibers and GML? Consist essentially of such fibers and GML? Note again the discussion in paragraphs 3 and 7. If the first and last, then the transitional language, i.e. “further comprising” in claim 15 is inconsistent. If the second and third, then the language “consisting essentially of” on lines 1-2 of claim 1 is inconsistent. See also the Claim Language Interpretation section and Response to Arguments section infra.

6. Claims 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 14 and 15 now claim the tampon comprising an absorbent structure consisting essentially of lyocell fibers or the absorbent structure consisting essentially of lyocell fibers, respectively, further comprising glycerol monolaurate, i.e. GML. Applicant cites page 7, lines 13-22 and page 10, lines 3-8 as support for such claimed combinations. However, while such portions of the application in addition to others teach a tampon consisting of lyocell fibers, i.e. a tampon or absorbent structure consisting of lyocell, or such lyocell fibers in combination with other materials, e.g. GML, i.e. a tampon comprising an absorbent structure comprising lyocell fibers and GML, this is not what is claimed. See also discussion in paragraphs 3 and 5 supra and

Art Unit: 3761

paragraph 7 infra. If Applicant maintains such claim language, the portion of the specification which provides support for the entire scope of the invention of each of the claims in a single embodiment should be set forth.

7. Claims 1-2 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in MPEP 2164.04, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written rejection. The language should focus on those factors, reasons and evidence that lead the examiner to conclude the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

First, what is the claimed invention? As set forth in claim 1 the invention is an absorbent tampon comprising an absorbent structure consisting essentially of lyocell fibers.

Second, the terminology “consisting essentially of” is interpreted to limit the scope of the absorbent structure to the specified fibers and that which does not materially affect the basic and novel characteristics of such absorbent structure.

Third, new claims 14-15 now claim such tampon or absorbent structure, respectively, further comprising glycerol monolaurate, i.e. GML, which as disclosed at, e.g., page 10 is, e.g., a pharmaceutically active compound. See the discussion in paragraphs 3 and 5-6.

However and fourth, the instant application does not set forth what such “basic and novel characteristic(s)” to be so affected are considered to be, e.g. the application only discloses specific densities and absorbencies of a tampon of specific dimensions consisting of lyocell fibers, not the “basic and novel characteristics” of an absorbent structure as claimed.

Finally, while pages 6-10 of the instant application set forth the composition of the absorbent structures, and thereby the tampons comprised thereof, as contemplated is not limited to only lyocell fibers but also combinations of such with other materials, e.g. both absorbent and non-absorbent, GML, i.e. a tampon comprising an absorbent structure comprising such combinations, which other materials have the capability of affecting characteristics of an absorbent structure, see, e.g. page 6, lines 19 et seq., it does not set forth the specifics of such combinations, i.e. what the exact compositions are, i.e. what the “basic and novel characteristics” of such combinations are and thereby, the absorbent structures composed thereof.

For these reasons and evidence, the examiner concludes the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. See also the Response to Arguments section *infra*.

Claim Language Interpretation

8. Claim 1 sets forth an absorbent tampon having a specific density and a specific Syngyna Absorbency. It is noted while the Test is described generally on page 11, lines 19-24, the specifics of such test have not been set forth nor are such specifics readily available to the Examiner nor has a copy of such FDA regulation been provided to the Examiner. See the prior art rejection and Response to Arguments section *infra*. Claim 1 further sets forth that the tampon comprises an absorbent structure consisting essentially of lyocell fibers. It is noted the tampon is not required to consist essentially of such fibers nor has the structure which does essentially consist of the fibers been defined as requiring more than at least two fibers. Furthermore, the terminology “consisting essentially of” limits the scope of the absorbent structure to the specified fibers and that which does not materially affect the basic and novel characteristics of such structure. However as set forth *supra* the instant application does not set forth what such “basic and novel characteristic(s)” of the absorbent structure to be so affected are considered to be. Note additionally the lack of clarity/consistency discussed *supra* also now with regard to claims 1 and 14-15. Therefore if a structure including at least two lyocell fibers is absorbent it will be interpreted to read on the claim language.

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodings et al PCT ‘133.

See '133 at abstract, the last paragraph of page 1, page 2 line 27-page 3, line 22, page 4, lines 20-32, page 5, second full paragraph, and thereby GB '637 at page 1, lines 103-110, '133 at page 7, lines 1-19 and page 9, i.e. '133 teaches an absorbent tampon comprising an absorbent structure "consisting essentially of" lyocell fibers, as best understood, see the Claim Language Interpretation section supra. The tampon has a density of about 0.3 to about 0.5 grams per cubic centimeter, i.e. about 0.35, and an absorbency of at least about 4.4 g/g as claimed in claim 1 and at least about 5g/g as claimed in claim 2, see Tables 1 and 3, e.g. No. 5 of Table 1. Applicant claims the absorbency is determined by the "well known Syngyna Test", see page 10, lines 15-18 and page 11, last paragraph, i.e. the absorbency is termed the "Syngyna Absorbency". It is the Examiner's first position that since the '133 reference teaches at page 5, lines 24-25, and thereby GB '637 at page 1, lines 103-108, assessing the tampon absorbency also by the known Syngyna test, i.e. the absorbency is termed the "Syngyna Absorbency" in '133 instead, that Tables 1 and 3 as discussed supra teach the claimed absorbencies. In any case, i.e. the Examiner's second position, since the tampon of '133 is made of an absorbent structure of lyocell fibers, as best understood, which fibers are processed as disclosed by the instant application, i.e. hydrothermally treated in a water bath of like temperature and time, and the tampon also has the claimed density, that there is sufficient factual evidence for one to conclude that such tampon would also inherently have the same absorbency when tested as disclosed by the instant application, if not already, i.e. have the same "Syngyna Absorbency". Note also the Response to Arguments section infra.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodings '133 in view of Huber et al '598.

Claims 14 and 15 now claim the tampon comprising an absorbent structure consisting essentially of lyocell fibers or the absorbent structure consisting essentially of lyocell fibers, respectively, further comprising glycerol monolaurate, i.e. GML. While '133 does not teach such GML, it does teach the desire to use the solvent spun cellulose/lyocell taught thereby for the manufacture of tampons. Note also '133 at page 4, lines 16-19 of '133. It is also noted that it is not clear whether page 7, lines 6-22 and col. 10, lines 3-11 set forth that such GML is a conventional additive/agent or not. Therefore, see Huber et al '598 at col. 1, line 4-col. 2, line 50, i.e. use of GML for the amelioration of toxic shock syndrome in tampons manufactured from lyocell fibers. Therefore, to employ GML in combination with the tampon manufactured from lyocell fibers, i.e. the absorbent structure, of '133 as taught by '598 would be obvious to one of ordinary skill in the art in view of the recognition that such would improve the safety of the lyocell tampons manufactured, i.e. ameliorate toxic shock syndrome, and the desire to '133 to manufacture lyocell tampons as well as the desire of safety associated with any tampon manufactured.

Response to Arguments

13. Applicant's remarks with regard to the matters of form on the first four pages of remarks have been considered but are either deemed moot in that they have not been repeated or are deemed not persuasive for the reasons set forth supra. In addition to such reasons it is specifically noted that pages 6-7 does not set forth the fibers and additives on pages 6-7 can be added to the absorbent structure without affecting properties/characteristics of the fibers, let alone the "basic and novel characteristics" of the structure/tampon. It is further noted that the Examiner is not requesting any additional information from the Applicant regarding the FDA test other than such has not been readily available to the Examiner nor provided by the Applicant and the rejection on prior art is to be viewed with such in mind. With regard to the arguments on the remaining pages of the remarks with regard to the prior art. Such remarks have been considered but are deemed narrower than the prior art at, e.g., page 5, lines 17-20 and the claim language. First the claims only require a density of a tampon not every density of a tampon be in the claimed range. Second, Applicant has based the calculations on the lengths after storage which lengths are the average of three tampons, see page 15, line 29. Third, the average density set forth on page 5, line 18 is that of a tampon of nominal length and diameter, i.e. an average of one tampon's density, not the average of a plurality of tampons as calculated by Applicant. It is further noted that that in Applicant's formula R is the radius not the diameter. At best Applicant's calculation of average density represents the average of twelve densities of which each of the twelve densities is an average of a density of three tampons after storage. The density as claimed is not so limited as best understood. As set forth supra '133 includes a density of a tampon within the claimed range.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

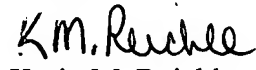
Any new grounds of rejection were necessitated by the addition of claims 14-15.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

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Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
August 9, 2007